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Effects of policosanol in older patients consuming Nitrates vasodilators

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Introduction: Policosanol is a cholesterol-lowering drug with concomitant antiplatelet effects. The efficacy and safety of policosanol have been investigated in clinical studies and post-marketing surveillance. Policosanol is very safe and no drug-related adverse events (AE) have been demonstrated, even in population subsets with high consumption of concomitant therapy, indicating that the potential risk of drug-drug interaction (DDI) for policosanol is low. Vasodilators are used in geriatric populations mainly to treat congestive heart failure and acute decompensating of heart failure, although associated with other anti-hypertensive are also used for manage arterial hypertension. Vasodilators, however, have the considerable risk of drug-related toxicity, the most frequent symptoms being those derived from excessive vasodilation and hypotension, such as nausea, vomiting, loss of consciousness and reflex tachycardia. Vasodilators show important DDI derive from pharmacodynamic interactions with several drugs, those associated with the concomitant use of other vasodilators and diuretics being the most relevant. Considering such facts, the interest to study putative DDI between policosanol and vasodilators is supported.

Objective: To investigate whether policosanol administered to older patients consuming vasodilators induces any specific disturbance on safety indicators and/or increase the frequency or severity of AE in such patients.

Methods: This report was based in the analysis of the records of all patients (185) taking nitrates vasodilators included in a Prevention Study in the Elderly randomized to policosanol 5 mg/d or placebo for 3 years. An analysis was by Intention-to-treat.

Results: Baseline characteristics were well balanced in both groups. After one year on treatment, policosanol lowered significantly low-density lipoprotein-cholesterol (LDL-C) (20,9 %), total cholesterol (TC) (15,9 %) and triglycerides (TG) (19,3 %), whereas raised high-density lipoprotein-cholesterol (HDL-C) (8,3 %). Policosanol effects persisted, even increased, during the 3 years treatment. At the end of the study, policosanol reduced LDL-C (35 %), TC (25 %), TG (19,3 %) and raised HDL-C (16,7 %). Of 185 randomized patients taking vasodilators, 44 (23,8 %) withdrew from the trial. The frequency of withdrawals in placebo (31/95; 32,6 %) was greater ($p<0,01$) than in policosanol group (13/90; 14,4 %). Overall, 26/185 (14,1 %) patients discontinued due to some AE: 23 placebo (24,2 %) and 3 (3,3 %) policosanol patients ($p<0,01$). Policosanol did not impair safety indicators compared with placebo but induced additional decreases in systolic pressure compared with placebo.The frequency of policosanol patients experiencing serious adverse events (SAE) (3/90; 3,3 %) was lower ($p<0,01$) than in respective placebo (23/95; 24,2 %). Likewise, the frequency of policosanol patients who experienced some mild or moderate AE during the study (10/90; 11,1 %) was lower ($p<0,05$) than in matched placebo (28/95; 29,5 %).

Conclusions: Policosanol was well tolerated in older subjects with high coronary risk-taking vasodilators, not impairing safety indicators or increasing any AE respect to placebo. Policosanol, however, produced additional decreases of arterial pressure and reduced the frequency of SAE compared with placebo. Cholesterol-lowering efficacy of policosanol was persistent and consistent with that expected. These results indicate that policosanol can be administered to older patients taking vasodilators without risk of relevant adverse DDI.